The SFDA Revoked the Marketing Authorization of Ritodrine (YUTOPAR®) in Saudi Arabia.
By: Naser A. Aljaser, B. Pharm, MSc.

On April 29, 2013, the Saudi Food and Drug Authority (SFDA) announced that the marketing authorization of ritodrine (Yutopar®) was revoked in Saudi Arabia. The SFDA decision was based on reviewing of clinical trials, meta-analyses and in-vitro studies that indicated that the risk of serious adverse events is significantly increased among users of ritodrine. Ritodrine has a direct relaxant effect on the smooth-muscle fibers of the myometrium and was used to suppress preterm labour.

The National Pharmacovigilance and Safety Centre has reviewed the safety and efficacy profiles of Yutopar® and has concluded that the risks associated with the use of this drug outweigh its benefits. In addition, it has been found that ritodrine is associated with several serious adverse effects such as Respiratory Distress Syndrome (RDS), fatal tachycardia and dyspnea. The Pharmacovigilance Advisory Committee also confirmed the unfavourable risk-benefit balance of Yutopar®. Therefore, the SFDA advises healthcare professionals that Yutopar® is no longer approved in Saudi Arabia and they should discuss with their patients the available alternatives.

The Use of Diane-35® (Ethinylestradiol/Cyproterone) and Risk of Thromboembolism.
By: Fawaz Alharbi, B. Pharm, MSc, CPP

Recently, the French Medicines Agency (ANSM) has announced that they decided to suspend the marketing authorisation for Diane 35® and its generics for acne treatment in France. This decision was based on review of known data by the French medicines agency. The agency found that Diane 35® and its generics carry a risk of thromboembolism, while their effectiveness in treating acne is moderate and there are other available alternatives. Therefore, The SFDA has carried out a comprehensive review to assess the benefit-risk balance of use of Diane 35® and concluded that:

1. The use of Diane-35® must be restricted to treatment of androgenization symptoms (symptoms caused by an increased effect of male sexual hormones) including hirsutism and moderate to severe acne, refractory to topical and oral antibiotic therapy.
2. The drug SHOULD NOT be used as a contraceptive in women who do not suffer from androgen-dependent conditions.
3. Diane-35® is a hormonal contraceptive. Women should not use it in combination with other hormonal contraceptives, as this will increase the dose of estrogen and as a result, a higher chance of developing thromboembolism.
The Risk of Rhabdomyolysis/Myopathy Associated with the Concomitant Use of Simvastatin and Gemfibrozil

By: Ali Y. Alshahrani, B.Pharm, and Yaser Alrdayaan B.Pharm, MSc.

The Saudi Food and Drug Authority (SFDA) has announced that the National Pharmacovigilance and Drug Safety Center (NPC) has completed an evaluation of the risk of rhabdomyolysis/myopathy when simvastatin and gemfibrozil are used concomitantly (drug-drug interaction).

The safety review process involved evaluation of world health organization (WHO) adverse drug reaction database, assessment of simvastatin periodic safety update report (PSUR), analysis of the pharmacokinetic properties of both medications and actions taken by international regulatory authorities.

The NPC found an increased rate of adverse events reporting of rhabdomyolysis and myopathy in those using simvastatin and gemfibrozil concomitantly. Gemfibrozil is a potent inhibitor of CYP3A4 enzyme which is responsible for simvastatin metabolism.

The SFDA concluded that the risk of rhabdomyolysis and/or myopathy increases with the concomitant use of simvastatin and gemfibrozil. Thus, the use of these medications concomitantly is now contraindicated and the NPC is working on the labeling update of both simvastatin and gemfibrozil’s contraindication sections.

Nanoparticles and Cosmetics

By: Abdulkareem a. Albabteen, B. Pharm, MSc.

Nanoparticles are particles sized between 1 and 100 nm that such range may be enlarged to account particles larger than 100 nm. Nanoparticles exhibit physicochemical properties that are different from the larger particles (1). Nanoparticles are not new and modern matter. They have been used by ancient Egyptians, Greeks and Romans in hair dye over 4000 years ago (2).

Nanoparticles usually are not registered as new substances and some of them have been approved by US Food Drug Administration (FDA) such as titanium dioxide and zinc oxide, which have been used in sunscreen. Cosmetic products which contain nanomaterials do not have to obtain the premarket approval (1,3). In 2006, the European Commission declared that 5% of cosmetic products in Europe contains nanoparticles (4). The German database of nano-products has registered 9 cosmetic products until 2010 (5). By 2015, the industry of nanotechnology in general would directly employ approximately two million workers with $1 trillion value (6).

Nanoparticles are elevating the development of cosmetic and skin care products to higher level. They have been mainly used in UV filters and delivery vehicles. Nanoparticles are being used to increase the penetration to the epidermis, enhance the stability of various cosmetic ingredients, make cosmetics more aesthetically pleasing and enhance the efficacy and tolerance of UV filters on the skin (5). Nanoparticles of Zinc Oxide (ZnO) and Titanium Dioxide (TiO2) are the main compounds used in the application of UV filters (4).

There are concerns about the long-term impact of using nanoparticles in cosmetic products. In 2005, Environmental Science and Technology Journal has published a research paper that declared that nanoparticles of zinc oxide were toxic to human lung cells (6). However, there is a lack of agreement between researchers about the safety of using nanomaterials for dermal use. Currently, FDA has a draft describing the safety assessment of using nanomaterials in cosmetic products. The draft declares that cosmetic products which contain nanomaterials must be labeled. Also, cosmetics manufacturers using nanomaterials apply the same legal requirements of other cosmetic manufactures. Furthermore, data needs and testing methods must be evaluated according to the properties or functions that may be exhibited by nanomaterials used in cosmetic products (3).

References

Formaldehyde

By: Mishal I. Al-Humaid, B.Pharm, MSc.

Formaldehyde is an organic compound with formula HCHO. It is colorless gas with a pungent odor. Used in many fields such as medical field (disinfectant and sterilizer), also it can be used in cosmetic field (as preservative).

When dissolved by water called “formalin” which in turn is used in hair straightener products at very low rates, and formaldehyde is added to help break the bonds in damaged hair at the presence of heat to facilitate the work of the keratin in the treatment of damaged hair. The harm of formaldehyde appears when it exceeds 0.2% based on the requirements of the safety of cosmetic products in the Gulf standard number GSO 1943/2009.

Saudi food and drug authority (SFDA) has effective regulatory role represented by executive directorate of cosmetic products safety in the detection of harmful of formaldehyde in keratin hair straightener. Where department has Post marketing surveillance to control cosmetic market.

How Formaldehyde produced in hair straightener?

Formalin substance used as a preservative for Keratin. But when heat is used in the process of hair straightening, the formalin material converted to formaldehyde (gas). And cause a lot of troubles for users.

Formaldehyde side effect:

- Disorders of the nervous system.
- Eye irritation.
- Respiratory disorders, such as: shortness of breath and severe cough.
- Irritation of the mucous membranes.
- Itching and redness of the skin.

The American studies and reports stated that formaldehyde exposure in the long term is likely to be a cause of cancer.

Recommendations for consumers and practitioners:

- Beware of counterfeit products and products that exceed the 0.2% formaldehyde.
- Hair straightening process should be in a well-ventilated room to avoid harmful fumes of formaldehyde.
- Mask should be used to reduce the harm to the respiratory system.
- In case of allergy process of hair straightening should be stopped and product mustn’t used again.
- Hair straightening process mustn’t be used for pregnant and children under 6 years.
- In case of allergy from any keratin hair straightener product report Saudi food and drug authority immediately.

Statins and the risk of developing diabetes

Overall benefits of statins still clearly outweigh potential risks

By: Abdulmohsen A. Al-Obaid, B. Pharm, MSc.

Statins are the cornerstone of treatment for dyslipidemia, but a recent meta-analysis of randomized trials found an association between their use and incident diabetes.

As the authors acknowledge, information on body weight, family history, and laboratory parameters was not available and could not be included in the analysis, which is an important limitation. Paradoxically, statins have been shown to reduce cardiovascular events in patients with diabetes, so these drugs play an important role in the treatment of these patients. Each 1 mmol/L reduction in low density lipoprotein-cholesterol achieved with statin treatment results in a 21% reduction in major vascular events and 9% reduction in total mortality over four years in patients with diabetes.

Statins have been suggested to have multiple pleiotropic actions, and their effects on glucose homeostasis and the cardiovascular system may be mediated through different mechanisms. The mechanism of the diabetogenic action of statins is still unclear, but—as has been suggested recently—statins may inhibit insulin secretion through their effects on pancreatic β cells.

References

Monoclonal Antibodies and Related Products Quality

By: Ibrahim G Algayadh, B. Pharm, MSc.

Saudi Food and Drug Authority (SFDA) has recently published “Monoclonal Antibodies and Related Products Quality Guideline”. It has been developed to assist applicants in the preparation and submission of monoclonal antibody drug applications.

The guideline designed to facilitate the development and expedite the review of monoclonal antibodies that are intended to be marketed in Saudi Arabia. This guideline lays down quality requirements for monoclonal antibodies.

Monoclonal antibodies are immunoglobulins (Ig) with a defined specificity secreted derived from a monoclonal cell line. Their biological activities are characterised by a specific binding characteristic to a ligand (commonly known as antigen), and may be dependent on immune effector function such as antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC). Monoclonal antibodies may be generated by recombinant DNA (rDNA) technology, hybridoma technology, B lymphocyte immortalisation or other technologies (e.g. display technology, genetically engineered animals).

This guideline covers principles and general requirements for development, production, characterisation and specifications for monoclonal antibodies to be used as, or in the production of human medicinal products. It also addresses quality issues for the marketing authorisation of monoclonal antibodies derived from a monoclonal cell line, and intended for therapeutic and prophylactic use (including ex vivo application), and in vivo diagnostic use.

Polyclonal antibodies (fractionated or recombinant) are outside the scope of this guideline, although its principles should be applied where appropriate.

The scope of this guideline does not include:

- Monoclonal antibodies to be used for diagnostic purposes in vitro;
- Monoclonal antibodies used in clinical trials. However, the principles described in this document should be taken into account in the production and control of monoclonal antibodies in clinical trials, and their applicability will be determined on a case-by-case basis.

References

- SFDA Guidelines for Production and Quality Control of Blood Products (Guidelines on Transmissible Spongiform Encephalopathies in Relation to Biological and Pharmaceutical Products).
- The following ICH Guidelines may be consulted:
  - International Conference on Harmonisation. ICH Q5B: Analysis of the Expression Construction in Cells Used for Production of R-DNA Derived Protein Products.
  - International Conference on Harmonisation. ICH Q6D: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products.
  - International Conference on Harmonisation. ICH Q6B: Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products.
- Further information can be found on the ICH homepage: http://www.ich.org

General

Vaccine safety:

By: Yaser S. Alrdayaan, B. Pharm, MSc.

The National Pharmacovigilance and Drug Safety Center (NPC) at the Saudi Food & Drug Authority is responsible for monitoring adverse events in Saudi Arabia. Small numbers of those adverse events reports is actually related to vaccines. According to the World Health Organization, Adverse Event Following Immunization (AEFI) is defined as “any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine”.

AEFI is divided into different classes:

- Vaccine product–related reactions. This class includes adverse events which may relate to one or more of the inherent properties of the vaccine products.
- Vaccine quality defect-related reactions. This class includes adverse events which may relate to one or more quality defects of the vaccine products including its administration device as provided by the manufacturer.
- Error-related reactions. This class is related to errors in vaccine handling, prescribing or administration. Therefore, it can be preventable. Some healthcare professionals are not welling to report such kind of errors because they think it is offensive.
- Anxiety-related reactions. This can occur due to anxiety about the immunization. It can be noticed in children or adults.
- The last class is coincidental events. A good example of coincidental event is a fever occurs at the time of the vaccination (temporal association) but is in fact caused by malaria.

In Saudi Arabia, we still face underreporting of AEFI. In the last statistics released by the National
Current Technique for Plasma Fractionation

By : Amr Y. Maqnas, B. Pharm, MSc.

Collected human plasma as a Therapeutic product known as Fresh Frozen Plasma (FFP), it is separated from whole blood by spinning down the donated blood unit (220-250 ml/unit) or by plasma aphaeresis (440-880 ml/unit). However, it is used as raw material for the production of pharmaceutical products called plasma derivatives; it goes through a complex, highly sterile and strict procedure to fractionate plasma protein.

This biologic substance contains hundreds of proteins such as Albumin (35 g/l), Immunoglobulin (10 g/l), Protease Inhibitors and the Coagulation factors. Currently about 20 different plasma protein therapeutics are used for treating life-threatening diseases or injuries associated to bleeding.

Plasma “Fractionation” is industrial processes that used to segregate therapeutic plasma proteins. Current plasma fractionation combine manufacturing steps for isolation and purification the rough fractions into individual therapeutic products. Viral inactivation and/or removal steps are present in the starting plasma pool.

This process need to have strictly regulatory standards because there is on zero risk in biological product. Blood/ Plasma collection, processing and storage for fractionation must be done by licensed/registered blood establishments (blood centers and aphaeresis collection centers) that are inspected and licensed by the relevant National Regulatory Authorities (NRAs), strict requirements are starting from the collection of plasma and include product manufacture and distribution steps. This article, review the main steps and good manufacturing practice applying in plasma fractionation.

I. Pre-industrial processing of plasma
   i. Donor screening, it is crucial to minimize the risk of infectious transmuted diseases. Donor behaviors and his/her medical history are important to detect his aptitude to donate. Saudi FDA as an authority body required that the health of a donor shall be determined by a licensed physician or under the direct supervision of a licensed physician, and donors shall be healthy persons of either sex between the ages of 18 and 65 years. In addition, a list of deferral and permanent excluded donor are pointed up in the “Guideline for Production and quality of blood product” which published by SFDA at 2010.

   ii. Collection methods may affect plasma quality. Precisely, avoidance of coagulation, complement, and fibrinolytic systems activation, which necessary to prevent generation of plasma proteases, is strictly acquired. As well as, impact on the recovery of the most labile proteins such as factor VIII.

   In consequence, to better preserve the integrity of plasma derived from whole blood, (a) immediate good mixing of the blood with the anticoagulant solution (a sodium citrate based solution); (b) the duration of the collection should not exceed 15 minutes; and (c) a few hours after donation, whole blood is subjected to a centrifugation that separates the cellular elements from plasma. As well, the SFDA guideline request that the aphaeresis procedure should be done under licensed physician supervision and strictly appeal “With aphaeresis procedures, care shall be taken to ensure that the maximum volume of erythrocytes is returned to the donor by intravenous infusion”.

References


Pharmacovigilance and Drug Safety Center, the reporting rate for adverse event following immunization was significantly low. Perhaps the reason of underreporting in vaccines is that public and healthcare professionals are not dealing with the vaccine as medicine. In other words, they do not assume that vaccine can cause adverse events like medicines. Therefore, more explanation to patients and parents need to be introduced during vaccination. Healthcare professionals are encouraged to provide such information about AEFI to the public. This behavior will increase the awareness of parents and they will be able to report such events. Also, the public will gain more trust about the vaccination program if they received enough information and have enough time to ask questions about vaccines and their possible risks related. Reporting adverse events for vaccines gives valuable information that improves the safety profile of vaccines.
iii. Testing of infectious agent

Pathogenic plasma-borne viruses include HIV, hepatitis C virus (HCV), hepatitis B virus (HBV), Hepatitis A virus (HAV), West Nile virus (WNV) and parvovirus B19 (B19). Parasites and intracellular viruses are not transmitted by plasma products because they are destroyed by freeze-thaw steps or removed by filtration steps used during the processing of fractionated products. The blood establishment and plasma fractionators, altogether, must be confirming the absence of serologic and/or genomic pathogenic viral markers. The SFDA Guideline requested “All final products shall be tested for viral marker and confirmatory ELISA and PCR assay and it shall be free from these pathogens”. Furthermore, sterility, identity, purity, pyrogenicity and safety tests are requested.

II. Industrial processing of plasma

Through a typical industrial fractionation scheme of standard plasma, Plasma pack (for a batch of 2000-4000 L, which needs about 3000-10,000 blood/plasma donor) are treated under highly sterile conditions then it thawed at 1°C to 4°C (from < -20°C as storage temperature). (Figure 1)

i. Cryoprecipitate is isolated using refrigerated continuous centrifuges, recovered from the centrifugation bowls and frozen at < -30°C for storage until further pooling and processing.

ii. The Cryo-poor plasma is immediately processed for primary chromatographic capture of labile coagulation factors such as the factor IX complex and its components. The pre-purified intermediates may be stored frozen until further processing.

iii. The coagulation factors/ anticoagulant-depleted plasma undergo sequential ethanol precipitation steps. This leads to successive precipitations of fibrinogen, IgG and albumin fractions, and intermediates for extraction of other therapeutic proteins, such as AAT (fraction IV-1), or IgM (fraction III). Depth filtration is preferred to centrifugation to separate precipitates and improve protein recovery. The fractionation of Hyper-immune plasma (eg, anti-rhesus) is usually performed on small plasma batch sizes, increasingly using full chromatographic processes to optimize the recovery of IgG.

Viral reduction treatments include inactivation steps (where viruses are “killed”) and removal steps (where viruses and proteins partition into distinct fractions). Use two distinct dedicated viral reduction treatments is the current “gold standard” for all plasma products. The first treatment is performed primarily to inactivate the pathogenic viruses, whereas the second reduction step targets non-enveloped viruses but also contributes to added safety against all agents. However, as viral removal treatment, nano-filtration is a specific viral filtration process applied to protein solutions using 15- to 75-nm multi-layers membranes, or equivalent systems, to remove viruses mostly by a sieving mechanism. Virus removal can also incidentally take place during protein precipitation, chromatography, or filtration steps.

In conclusion, plasma fractionation technology has increased in complexity over the years, with the greatest progresses in purification being associated with the use of updated methods that have made possible the development of new protein therapeutics and impressive improvements in product purity and quality. At the same time, several regulations and guidance have been issued by regulatory authority in different countries, which are updated as needed. Those cover important safety aspects required at all stages of the manufacturing chain.

References
The role of proteomics in plasma fractionation and quality of plasma-derived therapeutic proteins, Dajana Gaso-Sokac, Djuro Josic, Blood Transfusion, 2010, 8 suppl3: 86-91
Guidelines for Production and Quality Control of Blood Products, Drug sector, Saudi Food and Drug Authority, virgin 1.0, Aug 2010.
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المملصع العربي:

الهيئة العامة للغذاء والدواء تلغي تسجيل مستحضر
(ritodrine) Stabilan®

أعلنت الهيئة العامة للغذاء والدواء عن إلغاء تسجيل مستحضر
(ritodrine) الصيدلاني ريتودرين® والذي يستخدم في علاج الولادة
المبكرة حيث أشار تقرير صحري من إدارة الغذاء والدواء الأمريكية
(FAO) على منع إعطاء مستحضر ريتودرين في الحمل كمكمل للوقاية
الإكلينية وأعراض الإسهال (pulmonary edema) جانبيًا خطيرة مثل تراكم السوائل داخل الرئتين (pulmonary edema) ونقص التروية
(heart failure) في عدم استخدام الولادة وتدفق المخاط (pulmonary edema) والتسمم (pulmonary edema) ونقص التروية (cardiac arrhythmias) وانحلال العضلات (pulmonary edema)
(ribozyme). واستخدام البيوتال الكبيرة للأعراض المختلفة لدى الحوامل الثلاثات يتسبب في منع

Rhabdomyolysis:

فرصة الإصابة بمعرض احتلال العضلات

Rhabdomyolysis (Simvastatin, Gemfibrozil)

واعتلال العضلي (Myopathy)

بتوجه تداخل عند Simvastatin, Gemfibrozil

علومات مستحضر ديان (35)

Ethinylestradiol / Cyproterone

Diane 35®

كثرة الإصابة

المشترك في تجنيد التهاب العضلات (Rhabdomyolysis) (Ethinylestradiol / Cyproterone (Diane 35®) الوارد في دراسة هرمونات الذكورة (Androgens) والاحتلال المخاط (Simvastatin) (Hirsutism) (Ethinylestradiol / Cyproterone (Diane 35®) الشبوب المتطوع والحاج.

1 - استعداد المستحضر بتجهيز الشبوب المتوسط والحاج فقط عند

2 - عدم استخدام المستحضر كاملاً للحاج عند من لا تعاني من

الأعراض المذكورة أعلاه.

2 - لهذا المستحضر تأثير مانع للحاج عند استخدامه لعلاج الأعراض
المذكورة أعلاه. لذلك، إذا كان أخذك في اعتبار عند استخدام أي موانع
إضافية حيث أن ذلك يؤدي إلى زيادة جرعة الاستروجين وبالتالي زيادة
خطر الإصابة بتجهيز الأوعية الدموية.

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